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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,779	07/01/2003	Ming-De Deng	3161-18-2	6652
22442	7590	03/22/2006	EXAMINER	
SHERIDAN ROSS PC 1560 BROADWAY SUITE 1200 DENVER, CO 80202				RAMIREZ, DELIA M
		ART UNIT		PAPER NUMBER
		1652		

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,779	DENG ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-212 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) ____ is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) 1-212 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____ . |

DETAILED ACTION

Status of the Application

Claims 1-212 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-XXX. Claims 1-61, 207-212, drawn in part to a method to produce glucosamine or N-acetylglucosamine comprising culturing a microorganism which has at least one genetic modification that increases the activity of glucosamine-6-phosphate acyltransferase, wherein said microorganism is transformed with polynucleotides encoding the polypeptides of SEQ ID NO:30, 32, or 34, and is further transformed with polynucleotides encoding the polypeptides of SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, or 20, classified in class 435, subclass 84. For example, Group I comprises the subject matter described above wherein the microorganism is transformed with a polynucleotide encoding the polypeptides of SEQ ID NO:30 and 2, Group II comprises the subject matter described above wherein the microorganism is transformed with a polynucleotide encoding the polypeptides of SEQ ID NO:30 and 4, Group III comprises the subject matter described above wherein the microorganism is transformed with a polynucleotide encoding the polypeptides of SEQ ID NO:30 and 6, Group IV comprises the subject matter described above wherein the microorganism is transformed with a polynucleotide encoding the polypeptides of SEQ ID NO:30 and 8, etc.

XXXI. Claims 62-89, drawn in part to a method to produce glucosamine or N-acetylglucosamine comprising culturing a microorganism which comprises at

least one genetic modification that increases the activity of glucosamine-6-phosphate deaminase, wherein said microorganism is transformed with polynucleotides encoding the polypeptides of SEQ ID NO:42 and 30, classified in class 435, subclass 84.

- XXXII. Claims 62-89, drawn in part to a method to produce glucosamine or N-acetylglucosamine comprising culturing a microorganism which comprises at least one genetic modification that increases the activity of glucosamine-6-phosphate deaminase, wherein said microorganism is transformed with polynucleotides encoding the polypeptides of SEQ ID NO:42 and 32, classified in class 435, subclass 84.
- XXXIII. Claims 62-89, drawn in part to a method to produce glucosamine or N-acetylglucosamine comprising culturing a microorganism which comprises at least one genetic modification that increases the activity of glucosamine-6-phosphate deaminase, wherein said microorganism is transformed with polynucleotides encoding the polypeptides of SEQ ID NO:42 and 34, classified in class 435, subclass 84.
- XXXIV. Claims 90-105, 107, 207-212, drawn in part to a method to produce glucosamine or N-acetylglucosamine comprising culturing a microorganism which has at least one genetic modification that decreases the activity of glucosamine-6-phosphate deaminase, and at least one genetic modification that increases the activity of glucosamine-1-phosphate N-acetyltransferase, wherein said microorganism is transformed with a polynucleotide encoding the polypeptide of SEQ ID NO:2 and a polynucleotide encoding the polypeptide of SEQ ID NO: 56 or 58, classified in class 435, subclass 84.

XXXV-XLIII. Claims 90-107, 207-212, drawn in part to a method to produce glucosamine or N-acetylglucosamine comprising culturing a microorganism which has at least one genetic modification that decreases the activity of glucosamine-6-phosphate deaminase, and at least one genetic modification that increases the activity of glucosamine-1-phosphate N-acetyltransferase, wherein said microorganism is transformed with a polynucleotide encoding the polypeptide of SEQ ID NO:4, 6, 8, 10, 12, 14, 16, 18, 20 and a polynucleotide encoding the polypeptide of SEQ ID NO: 56 or 58, classified in class 435, subclass 84. For example, Group XXXV comprises the subject matter described above wherein the microorganism is transformed with a polynucleotide encoding the polypeptides of SEQ ID NO:4 and a polynucleotide encoding the polypeptides of SQ ID NO: 56 or 58, Group XXXVI comprises the subject matter described above wherein the microorganism is transformed with a polynucleotide encoding the polypeptides of SEQ ID NO:6 and a polynucleotide encoding the polypeptides of SQ ID NO;56 or 58, Group XXXVII comprises the subject matter described above wherein the microorganism is transformed with a polynucleotide encoding the polypeptides of SEQ ID NO:8 and a polynucleotide encoding the polypeptides of SQ ID NO;56 or 58, etc.

XLIV. Claims 108-112, 114-115, 207-212, drawn in part to a method to produce glucosamine or N-acetylglucosamine comprising culturing a microorganism which comprises an endogenous glucosamine-6-phosphate acetyltransferase and at least one genetic modification to increase the activity of glucosamine-6-phosphate synthase, wherein said microorganism is transformed with a polynucleotide encoding the polypeptide of SEQ ID NO:2, classified in class

435, subclass 84.

- XLV-LIII. Claims 108-115, 207-212, drawn in part to a method to produce glucosamine or N-acetylglucosamine comprising culturing a microorganism which comprises an endogenous glucosamine-6-phosphate acetyltransferase and at least one genetic modification to increase the activity of glucosamine-6-phosphate synthase, wherein said microorganism is transformed with a polynucleotide encoding the polypeptide of SEQ ID NO:4, 6, 8, 10, 12, 14, 16, 18, 20, classified in class 435, subclass 84.
- LIV. Claims 116-119, drawn to a genetically modified microorganism comprising at least one modification that increases the activity of glucosamine-6-phosphate acetyltransferase, classified in class 435, subclass 252.3.
- LV. Claims 120-125, drawn to a genetically modified microorganism comprising at least one modification that increases the activity of glucosamine-6-phosphate deaminase, classified in class 435, subclass 252.3.
- LVI. Claims 126-127, drawn to a genetically modified microorganism comprising at least one modification that decreases the activity of glucosamine-6-phosphate deaminase, and at least one modification that increases the activity of glucosamine-1-phosphate N-acetyltransferase, classified in class 435, subclass 252.3.
- LVII. Claims 128-156, drawn to a method to recover N-acetyltransferase from a fermentation broth, classified in class 435, subclass 274.
- LVIII. Claims 157-206, drawn to a method to chemically produce glucosamine from N-acetylglucosamine, classified in class 536, subclass 55.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-LVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the microorganisms of Inventions LIV-LVI can be used in the methods of Inventions I-LIII, to produce glucosamine-6-phosphate deaminase, glucosamine-1-phosphate N-acetyltransferase, glucosamine-6-phosphate acetyltransferase, and/or glucosamine-6-phosphate synthase, as well as to produce endogenous compounds naturally found in those organisms.
3. Inventions I-LIII, LVII-LVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, while the methods of Inventions I-LIII, LVIII are methods to produce glucosamine and/or N-acetylglucosamine, each of the methods of Inventions I-LIII use organisms comprising different genetic modifications, whereas the method of Invention LVIII produces glucosamine by chemical synthesis. The method of Invention LVII is unrelated to the methods of Inventions I-LIII, LVIII as it is a method to purify N-acetylglucosamine from a fermentation broth. Therefore, the methods of Inventions I-LIII, LVII-LVIII comprise different steps, use different products, and/or produce different results.
4. Inventions LIV-LVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the microorganisms of Inventions LIV-LVI have different genetic modifications which have different effects on those organisms, have not been disclosed as capable of use together, and have different functions.

5. As set forth in MPEP § 803, the criteria for a proper restriction between patentably distinct inventions requires that the inventions must be independent or distinct as claimed, and a search of all the inventions would impose a serious burden on the examiner. Groups I-LVIII have been shown to be independent or distinct, for the reasons set forth above. MPEP § 803 also indicates that a serious burden on the examiner may be *prima facie* shown if the Examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. The inventions of Groups I-LVIII have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification. In addition, a search of all the inventions would require at a minimum a separate patented/non-patented literature search, a class/subclass search, and a sequence search. These searches are not all co-extensive. Therefore a comprehensive examination of all groups would impose an undue burden on the Examiner. Thus, restriction for examination purposes as indicated is proper.

6. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

7. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected

product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
March 14, 2006